

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
David H. REIFSNYDER *et al.*) Group Art Unit: 1656
Serial No.: 10/753,078) Examiner: Carlson, Karen C.
Filed: January 8, 2004) Atty. Dkt. No.: 012441.00050 (51486-US-NP)

CONFIRMATION NO. 6550

For: IMPROVED METHOD OF PURIFYING TFPI AND TFPI ANALOGS

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. § 1.705(b)

U.S. Patent and Trademark Office
401 Dulany Street
Alexandria, VA 22314

Sir:

According to 37 C.F.R. § 1.705(b), Applicants hereby request a patent term adjustment under 35 U.S.C. § 154(b) of **360 days** for the above-captioned patent application. This Request is being filed with the payment of the issue fee, as provided in 37 C.F.R. § 1.705(b).

- A copy of the **Patent Term Adjustment History** for the above-captioned patent application, as downloaded from the public Patent Application Information Retrieval (PAIR) system, accompanies this Request.

(1) Fee

According to 37 C.F.R. § 1.705(b)(1), please charge the \$200 fee set forth in 37 C.F.R. § 1.18(e) to our Deposit Account No. 19-0733. Please debit or credit our Deposit Account No. 19-0733, as needed, for any additional fees or overpayment.

(2) Statement of the Facts Involved

(i) Correct Patent Term Adjustment

Page 3 of the Notice of Allowance mailed March 12, 2010 indicates a patent term adjustment of 0 days, but the correct patent term adjustment is **360 days**, based on the following facts:

Patent Term Adjustment History

The accompanying Patent Term Adjustment History, obtained from the public Patent Application Information Retrieval (PAIR) system, provides the basis for the incorrect 0-day patent term adjustment, as determined by the US Patent Office. In particular, page 2 of 3 of this document attributes **94 days of applicant delay** to the filing of an Information Disclosure Statement (IDS) on February 16, 2006. However, there are **no grounds under 37 C.F.R. § 1.704** for reducing the period of adjustment due to the filing of this IDS.

Case Law

In *Wyeth v. Dudas*, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. § 154(b)(2), concerning time periods used to calculate patent term adjustment. The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. § 154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. § 154.

In the opinion, the Court stated that “the PTO’s view is that any administrative delay under 35 § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under 35 § 154(b)(1)(B): the Applicant gets credit for ‘A delay’ or for ‘B delay,’ whichever is larger, but never A + B.” However, Plaintiff Wyeth argued that the § 154(b)(2)(A) and § 154(b)(2)(B) period overlap only if they occur on the same calendar day or days. The court determined that Wyeth’s construction of § 154(b)(2) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. § 154(b)(2)(A) **only** occurs if a 35 U.S.C. § 154(b)(1)(A) period and a 35 U.S.C. § 154(b)(1)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. § 154(b)(1)(A) period that falls outside of the 35 U.S.C. § 154(b)(1)(B) period **in addition to** the 35 U.S.C. § 154(b)(1)(B) period itself.

(ii) Relevant Dates as Specified in 37 C.F.R. §§ 1.703(a) through (e)

A. Period of Adjustment under 37 C.F.R. § 1.703(a)

According to 37 C.F.R. § 1.703(a), the period of adjustment is the sum of periods set forth under 37 C.F.R. § 1.703(a)(1) through 37 C.F.R. § 1.703(a)(6).

37 C.F.R. § 1.703(a)(1)

The date on which the application was filed under 35 U.S.C. § 111(a) is January 8, 2004. An action under 35 U.S.C. § 132, namely a Restriction Requirement, was mailed on November 1, 2005. The period of adjustment under 37 C.F.R. § 1.703(a)(1) is “The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. § 111(a)...and ending on the date of mailing of...an action under 35 U.S.C. § 132...”

The Period of Adjustment under 37 C.F.R. § 1.703(a)(1) is therefore 238 days running from March 9, 2005 to November 1, 2005.

37 C.F.R. § 1.703(a)(2)

A response to a non-final action under, or reply under 37 C.F.R. § 1.111, was filed on May 23, 2008 and an action under 35 U.S.C. § 132, namely a non-final rejection, was mailed on October 7, 2008. The period of adjustment under 37 C.F.R. § 1.703(a)(2) is “The number of days, if any, in the period beginning on the day after the date that is that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of...an action under 35 U.S.C. 132...”

The Period of Adjustment under 37 C.F.R. § 1.703(a)(2) is therefore 14 days running from September 24, 2008 to October 7, 2008.

The sum of the periods under 37 C.F.R. § 1.703(a)(1) through 37 C.F.R. § 1.703(a)(6) is the sum of 238 days under 37 C.F.R. § 1.703(a)(1) and 14 days under 37 C.F.R. § 1.703(a)(2). **The period of adjustment under 37 C.F.R. § 1.703(a) is therefore 252 days, running from March 9, 2005 to November 1, 2005 and from September 24, 2008 to October 7, 2008.**

B. Period of Adjustment under 37 C.F.R. § 1.703(b)

As indicated above, the date on which the application was filed under 35 U.S.C. § 111(a) is January 8, 2004. A Request for Continued Examination under 35 U.S.C. § 132(b) was filed December 23, 2007. According to 37 C.F.R. § 1.703(b), “The period of adjustment...is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. § 111(a)...and ending on the date a patent was issued, but not including...(1) The number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed and ending on the date the patent was issued.”

A patent has not yet issued. However, regardless of the date the patent issues, the period of adjustment under 37 C.F.R. § 1.703(b) is the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. § 111(a) and ending on the date on which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed. **The period of adjustment under 37 C.F.R. § 1.703(b) is therefore 349 days running from January 9, 2007 to December 23, 2007.**

C. Adjustment as Specified in 37 C.F.R. § 1.703(f) to which the Patent is Entitled

Under 37 C.F.R. § 1.703(f), “The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a)-(e) of this section, to the extent that such periods are not overlapping, less the sum of the periods calculated under 37 C.F.R. § 1.704.”

The sum of the periods under paragraphs (a)-(e) of 37 C.F.R. § 1.703 is the sum of 252 days under 37 C.F.R. § 1.703(a) and 349 days under 37 C.F.R. § 1.703(b), or 601 days. These periods do not overlap during any calendar days, *i.e.*, there is no overlapping period. Therefore, the non-overlapping sum of the periods under paragraphs (a)-(e) of 37 C.F.R. § 1.703 is 601 days. Also, as noted above, the adjustment is further reduced by the sum of the periods calculated under 37 C.F.R. § 1.704. The sum of these periods, detailed below, is 241 days.

Therefore, the adjustment under 37 C.F.R. § 1.703(f) to which the patent is entitled is 601 days minus 241 days or **360 days**.

(iii) Terminal Disclaimer

The application is not subject to a Terminal Disclaimer.

(iv)(A) Circumstances under 37 C.F.R. § 1.704

Under 37 C.F.R. § 1.704(b), “...the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed.” The following periods are therefore relevant with respect to 37 C.F.R. § 1.704:

(1) The period of **62 days** from April 25, 2007 to June 25, 2007, namely beginning on the day after the date that is three months after the January 24, 2007 mailing date of the Final Office Action and ending on the date the Notice of Appeal was filed;

(2) The period of **30 days** from April 24, 2007 to May 23, 2008, namely beginning on the day after the date that is three months after the January 23, 2008 mailing date of the Non-final Office Action and ending on the date the reply was filed.

(3) The period of **89 days** from January 8, 2009 to April 6, 2009, namely beginning on the day after the date that is three months after the October 7, 2008 mailing date of the Non-final Office Action and ending on the date the reply was filed.

(4) The period of **60 days** from December 26, 2009 to February 23, 2010, namely beginning on the day after the date that is three months after the September 25, 2009 mailing date of the Final Office Action and ending on the date the reply was filed.

The sum of the periods under 37 C.F.R. § 1.704 is therefore 241 days. This sum is used in determining the number of days of adjustment, set forth above, to which the patent is entitled under 37 C.F.R. § 1.703(f).

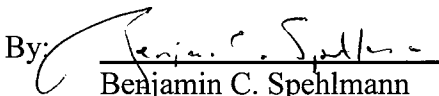
CONCLUSION

Applicants therefore respectfully request reconsideration of the patent term adjustment of 0 days, as indicated in the Notice of Allowance mailed August 20, 2009. The correct patent term adjustment is **360 days**, for the detailed reasons stated above.

Please continue to direct all correspondence in this application to Novartis Vaccines and Diagnostics, Inc. at the address provided for Customer No. 27476.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Date: June 14, 2010

By: 
Benjamin C. Spehlmann
Registration No. 45,649

Customer No. 22907



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10/753,078

METHOD OF PURIFYING TFPI AND TFPI ANALOGS

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Select New Case	Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Continuity Data	Published Documents	Address & Attorney/Agent	Supplemental Content
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Patent Term Adjustment

Filing or 371(c) Date:	01-08-2004	USPTO Delay (PTO) Delay (days):	-
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	-	Applicant Delay (APPL) Delay (days):	-
Post-Issue Petitions (days):	-	Total Patent Term Adjustment (days):	0
USPTO Adjustment (days):	-	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
03-12-2010	Mail Notice of Allowance		
03-11-2010	Document Verification		
03-11-2010	Notice of Allowance Data Verification Completed		
03-11-2010	Case Docketed to Examiner in GAU		
03-03-2010	Date Forwarded to Examiner		
02-23-2010	Amendment after Final Rejection		60
02-23-2010	Request for Extension of Time - Granted		⬆
01-15-2010	Mail Advisory Action (PTOL - 303)		⬆
01-14-2010	Advisory Action (PTOL-303)		⬆
01-05-2010	Date Forwarded to Examiner		⬆
12-28-2009	Amendment after Final Rejection		⬆
09-25-2009	Mail Final Rejection (PTOL - 326)		⬆
09-24-2009	Final Rejection		
08-11-2009	Date Forwarded to Examiner		
06-18-2009	Response after Non-Final Action		
05-20-2009	Mail Non-Final Rejection		
05-20-2009	Non-Final Rejection		
04-20-2009	Date Forwarded to Examiner		
04-06-2009	Response after Non-Final Action		89
04-06-2009	Request for Extension of Time - Granted		⬆
10-07-2008	Mail Non-Final Rejection	14	
10-01-2008	Non-Final Rejection	⬆	
12-15-2008	Case Docketed to Examiner in GAU	⬆	
11-14-2008	Case Docketed to Examiner in GAU	⬆	
04-10-2008	Information Disclosure Statement considered	⬆	
04-10-2008	Information Disclosure Statement (IDS) Filed	⬆	
07-16-2008	Date Forwarded to Examiner	⬆	
05-23-2008	Response after Non-Final Action		30
05-23-2008	Request for Extension of Time - Granted		⬆
04-10-2008	Information Disclosure Statement (IDS) Filed		⬆
01-23-2008	Mail Non-Final Rejection		⬆
01-18-2008	Non-Final Rejection		
01-07-2008	Case Docketed to Examiner in GAU		
01-04-2008	Date Forwarded to Examiner		
01-04-2008	Date Forwarded to Examiner		
01-04-2008	Disposal for a RCE / CPA / R129		
12-23-2007	Request for Extension of Time - Granted		
12-23-2007	Workflow - Request for RCE - Begin		
09-14-2007	Case Docketed to Examiner in GAU		

06-25-2007	Notice of Appeal Filed	62
06-25-2007	Request for Extension of Time - Granted	⬆
01-24-2007	Mail Final Rejection (PTOL - 326)	⬆
01-22-2007	Final Rejection	
11-17-2006	Date Forwarded to Examiner	
11-08-2006	Response after Non-Final Action	
08-08-2006	Mail Non-Final Rejection	
08-04-2006	Non-Final Rejection	
02-16-2006	Information Disclosure Statement considered	
05-26-2006	Date Forwarded to Examiner	
05-23-2006	Response after Non-Final Action	
02-16-2006	Reference capture on IDS	
02-16-2006	Information Disclosure Statement (IDS) Filed	
02-16-2006	Information Disclosure Statement (IDS) Filed	
02-23-2006	Mail Non-Final Rejection	⬆
02-21-2006	Non-Final Rejection	⬆
01-10-2005	Information Disclosure Statement considered	⬆
12-07-2005	Date Forwarded to Examiner	⬆
11-14-2005	Response to Election / Restriction Filed	⬆
11-01-2005	Mail Restriction Requirement	238
10-31-2005	Requirement for Restriction / Election	⬆
06-28-2005	Case Docketed to Examiner in GAU	⬆
01-10-2005	Reference capture on IDS	⬆
01-10-2005	Information Disclosure Statement (IDS) Filed	⬆
01-10-2005	Information Disclosure Statement (IDS) Filed	⬆
07-08-2004	IFW TSS Processing by Tech Center Complete	⬆
07-08-2004	Case Docketed to Examiner in GAU	⬆
07-09-2004	Change in Power of Attorney (May Include Associate POA)	⬆
07-08-2004	Correspondence Address Change	⬆
05-24-2004	Oath or Declaration Filed (Including Supplemental)	⬆
06-04-2004	Application Return from OIPE	⬆
06-04-2004	Application Return TO OIPE	⬆
06-04-2004	Application Return from OIPE	⬆
06-04-2004	Application Is Now Complete	⬆
05-21-2004	Payment of additional filing fee/Preexam	⬆
06-04-2004	Pre-Exam Office Action Withdrawn	⬆
06-04-2004	Application Return TO OIPE	⬆
06-03-2004	Application Dispatched from OIPE	⬆
06-04-2004	Application Is Now Complete	⬆
01-08-2004	Claim Preliminary Amendment	⬆
05-21-2004	CRF Disk Has Been Received by Preexam / Group / PCT	⬆
05-21-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	⬆
04-21-2004	CRF Is Good Technically / Entered into Database	⬆
03-23-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⬆
01-08-2004	CRF Disk Has Been Received by Preexam / Group / PCT	⬆
03-02-2004	Cleared by OIPE CSR	⬆
02-02-2004	CRF Is Flawed Technically / Not Entered into Database	⬆
01-30-2004	IFW Scan & PACR Auto Security Review	⬆
01-08-2004	CRF Disk Has Been Received by Preexam / Group / PCT	⬆
01-08-2004	Initial Exam Team nn	⬆

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